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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,391	11/12/2003	Randal Eckert	061818-5512US02	5819

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/706,391

Applicant(s)

ECKERT ET AL.

Examiner

Robert A. Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-5, 10-11, 13-20 and 24-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Pseudomonas*, classified in class 530, subclass 350.
- II. Claims 2-3, 6-7, 13, 18-20 and 22-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Staphylococcus*, classified in class 530, subclass 350.
- III. Claims 2-3, 8-9, 12-13, 18-20 and 24-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Escherichia coli*, classified in class 530, subclass 350.
- IV. Claims 24-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Shigella dysenteriae*, classified in class 530, subclass 350.
- V. Claims 24-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Salmonella typhimurium*, classified in class 530, subclass 350.
- VI. Claims 24-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Streptococcus pneumoniae*, classified in class 530, subclass 350.

- VII. Claims 26-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Candida albicans*, classified in class 530, subclass 350.
- VIII. Claims 26-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Cryptococcus neoformans*, classified in class 530, subclass 350.
- IX. Claims 26-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Candida krusei*, classified in class 530, subclass 350.
- X. Claims 26-27, drawn to compositions comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Helicobacter pylori*, classified in class 530, subclass 350.
- XI.. Claim 32, drawn to methods of treating a *Staphylococcus mutans* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Staphylococcus mutans*, classified in class 514, subclass 2.
- XII.. Claim 33, drawn to methods of treating a *Candida albicans* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Candida albicans*, classified in class 514, subclass 2.
- XIII.. Claim 34, drawn to methods of treating a *Helicobacter pylori* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide

moiety wherein the targeting moiety binds to *Helicobacter pylori*, classified in class 514, subclass 2.

- XIV. Claim 34, drawn to methods of treating a *Campylobacter jejuni* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Campylobacter jejuni*, classified in class 514, subclass 2.
- XV.. Claim 34, drawn to methods of treating a *Vibrio cholerae* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Vibrio cholerae*, classified in class 514, subclass 2.
- XVI.. Claim 34, drawn to methods of treating a salmonella infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to salmonella, classified in class 514, subclass 2.
- XVII.. Claim 34, drawn to methods of treating a *Shigella* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Shigella*, classified in class 514, subclass 2.
- XVIII.. Claim 34, drawn to methods of treating a *Escherichia coli* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Escherichia coli*, classified in class 514, subclass 2.

- XIX.. Claim 35, drawn to methods of treating a *Porphyromaonas gingivalis* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Porphyromaonas gingivalis*, classified in class 514, subclass 2.
- XX.. Claim 35, drawn to methods of treating a *Actinomyces* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Actinomyces*, classified in class 514, subclass 2.
- XXI.. Claim 35, drawn to methods of treating a *Veillonella* spirochete infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Veillonella* spirochete, classified in class 514, subclass 2.
- XXII.. Claim 35, drawn to methods of treating a gram-negative flora infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to gram-negative flora, classified in class 514, subclass 2.
- XXIII.. Claim 36, drawn to methods of treating a *Clostridium difficile* infection utilizing a composition comprising a targeting moiety coupled to an anti-microbial peptide moiety wherein the targeting moiety binds to *Clostridium difficile*, classified in class 514, subclass 2.
- XXIV. Claims 37-46, drawn to targeting peptides comprising SEQ ID NO:X, classified in class 530, subclass 350.

Art Unit: 1645

Claims 1 and 21 is a linking claim, linking the inventions of claims 2- 20 and 22-27 and claims 28-31 are linking claims linking the inventions of claims 32-37. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicant are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or a divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Applicant must further elect a single SEQ ID NO. (See MPEP 803.04).

Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-X and XXIV are separate and distinct from each other, as they comprise differing biochemical and immunological entities having differing properties and uses. Each invention constitutes a patentably distinct antigenic composition

Art Unit: 1645

Inventions XI-XXIII are each separate and distinct from each other as they are drawn to differing methods having different steps, different goals and leading to differing results.

Inventions II and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case compositions of Invention II can be used to produce antibodies.

Inventions VII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case compositions of Invention VII can be used to produce antibodies.

Inventions V and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case compositions of Invention V can be used to produce antibodies.

Inventions IV and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

Art Unit: 1645

§ 806.05(h)). In the instant case compositions of Invention IV can be used to produce antibodies.

Inventions III and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case compositions of Invention III can be used to produce antibodies.

Inventions X and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case compositions of Invention X can be used to produce antibodies.

Aside from the combinations listed above none of the compositions of Inventions I-X and XXIV can be used in the methods of Inventions XI-XXIII.

Because these inventions are distinct for the reasons given above and the search required for various groups would not be coextensive in scope, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1645

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

Art Unit: 1645

103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday - Thursday 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT A. ZEMAN
PATENT EXAMINER

December 26, 2005